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(54) **Female urinary incontinence device**

(57) A female urinary incontinence device including a periurethral cup (11), an external pad (12), and an elastic tubular bellows (13) extending therebetween, as well as associated elements (23) for holding the device in place and for collecting urine flowing therethrough. The periurethral cup is moulded in one piece from soft compressible material and has walls (19) of substantial thickness providing smoothly rounded surfaces (11a) for sealingly contacting surfaces of the periurethral floor and vaginal introitus. One wall portion of the cup curves upwardly to define a resilient urine-deflecting protuberance (20) received within the vaginal introitus. The device also includes a conduit (14) for directing urine to a collector (15), and may include a valved port for allowing air to enter the system within the external pad to prevent the development of relative negative pressure within that system, and vent for allowing gas to escape from the collector.

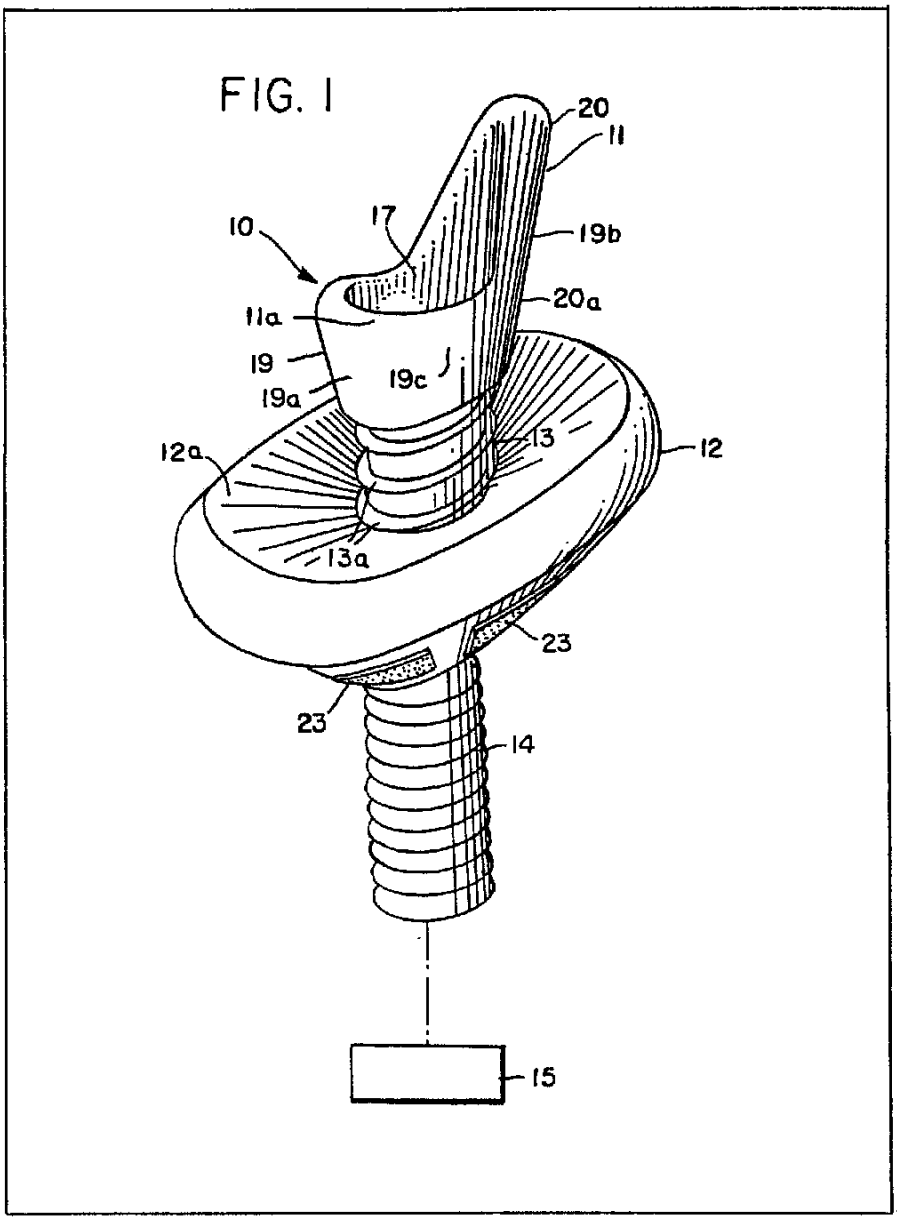

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FIG. 1

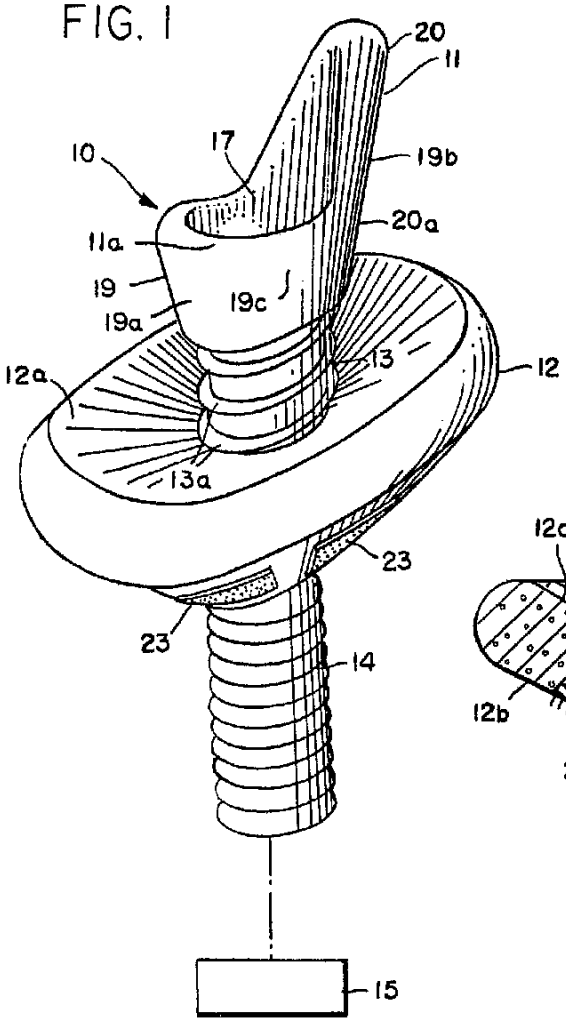


FIG. 2

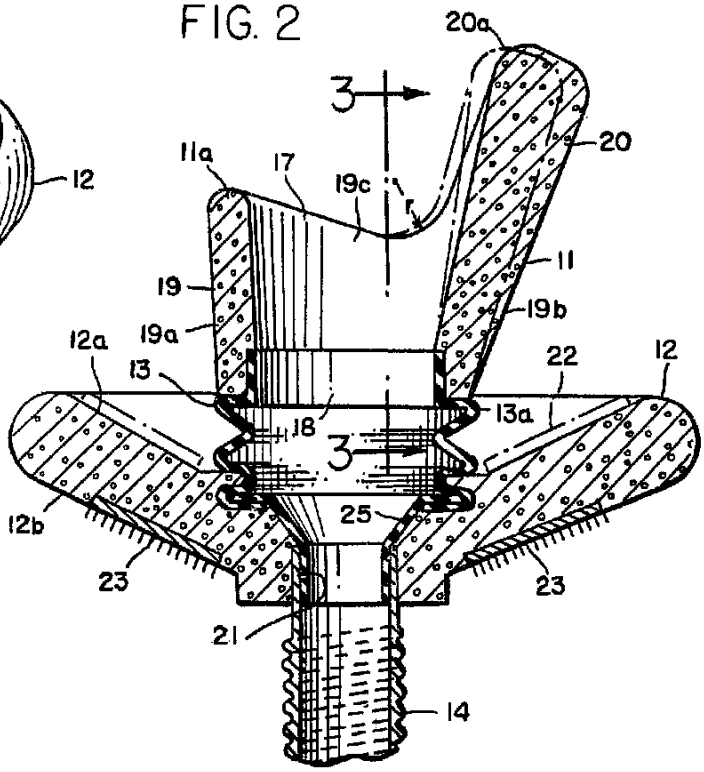
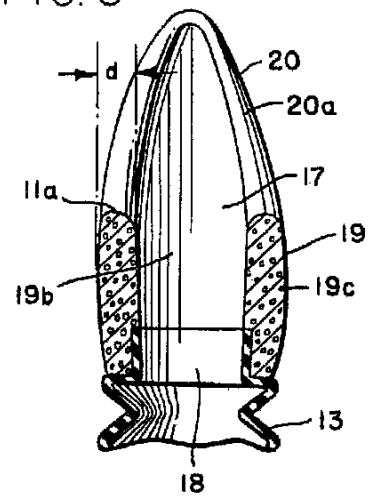


FIG. 3



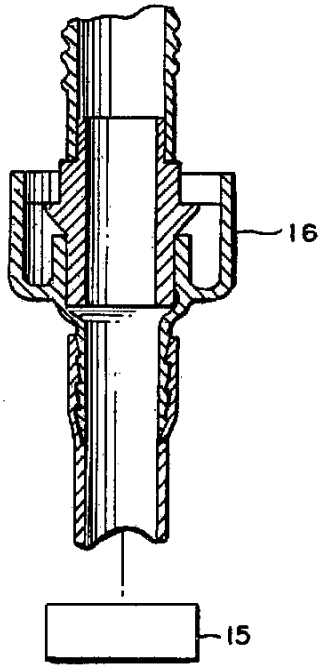


FIG. 4

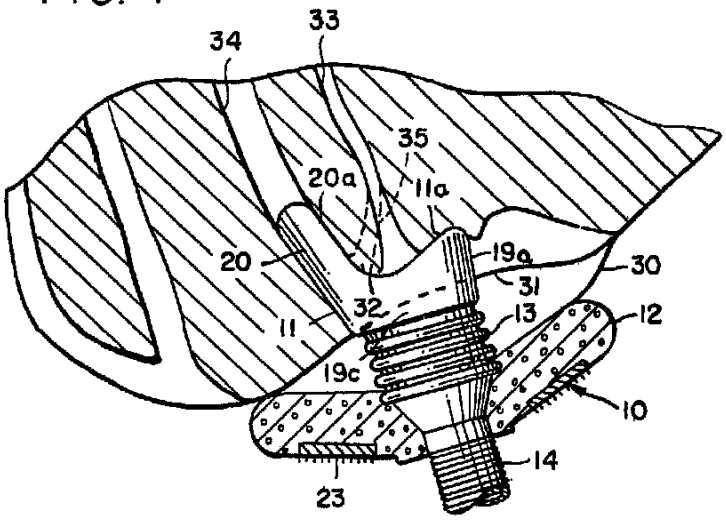


FIG. 5

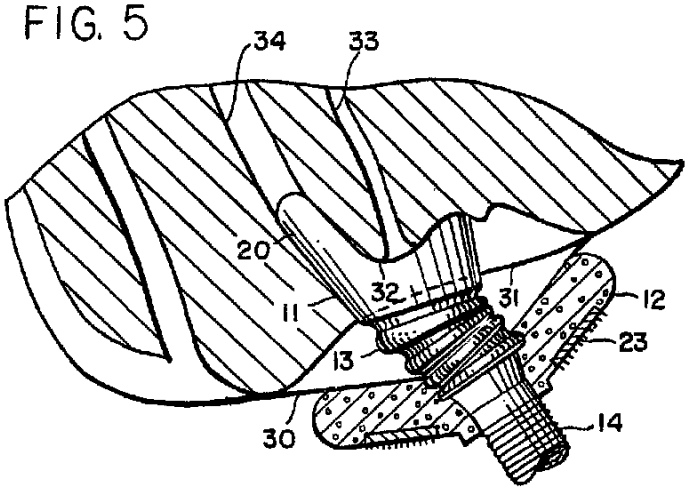


FIG. 6

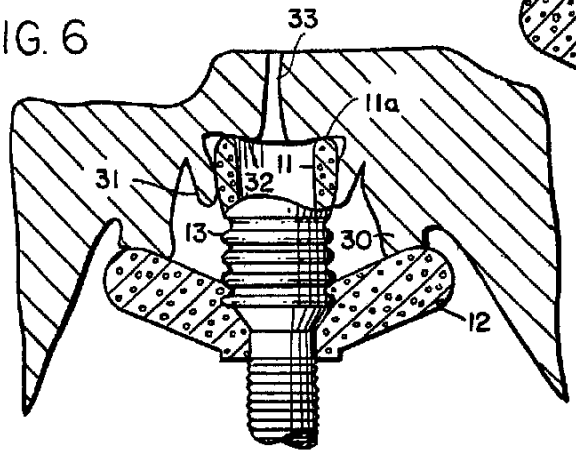


FIG. 7

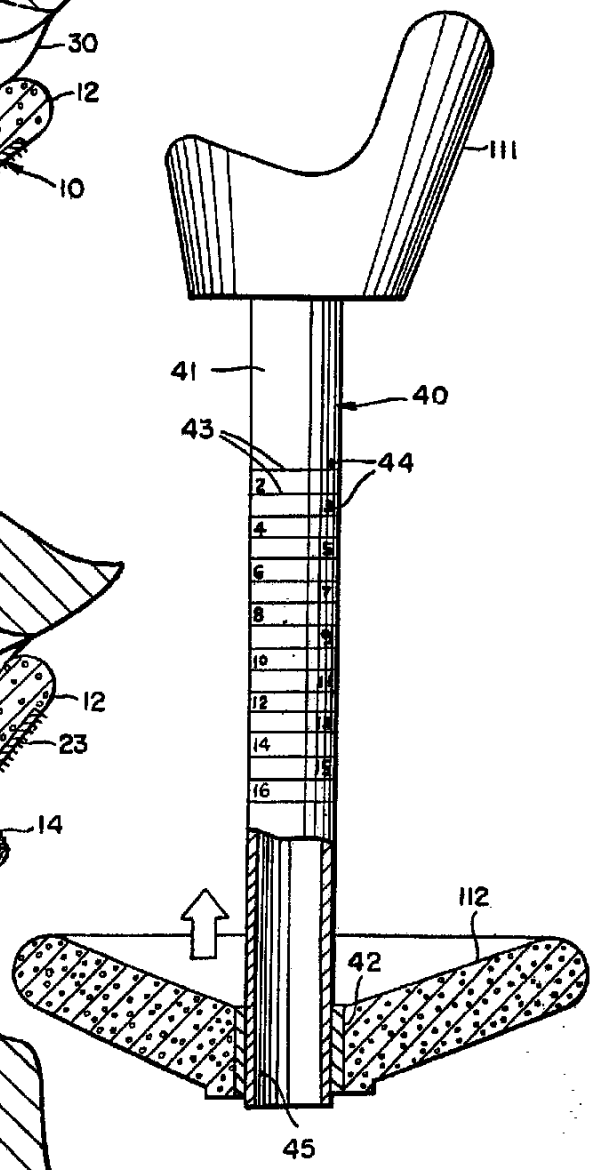


FIG. 8

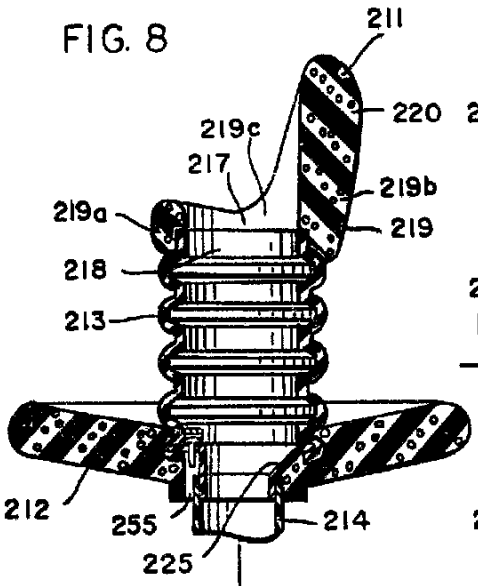
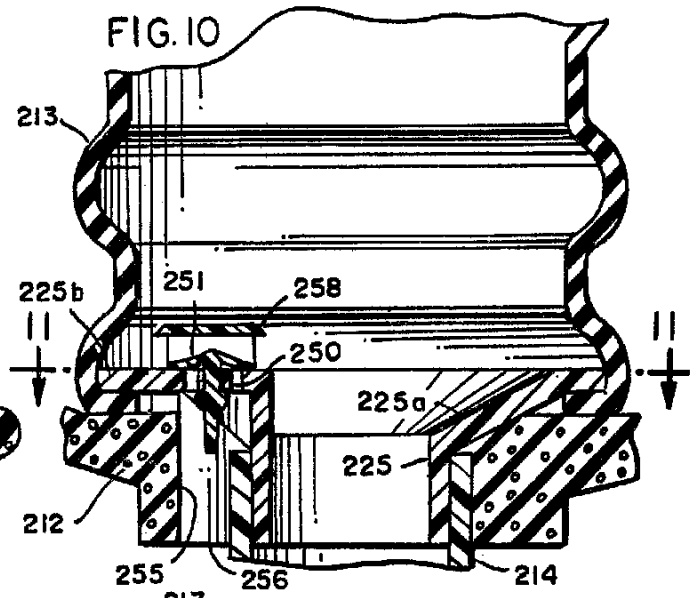


FIG. 10



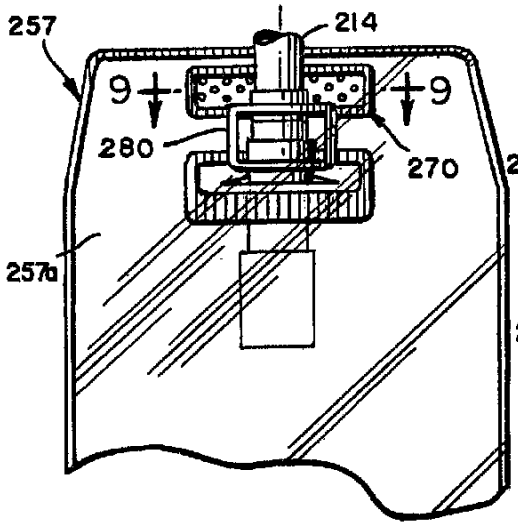


FIG. 11

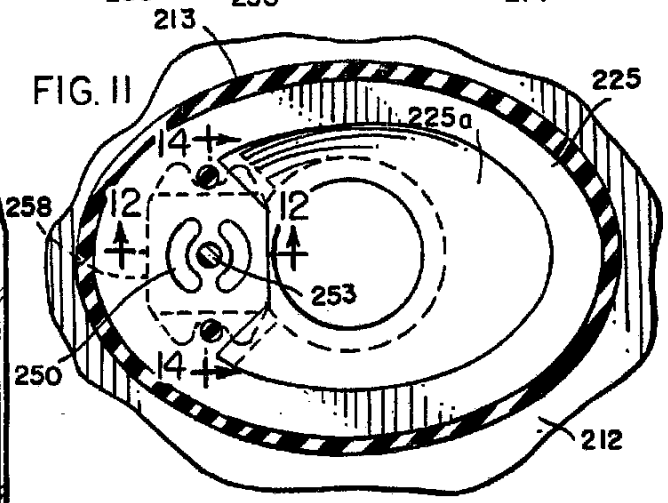


FIG. 12

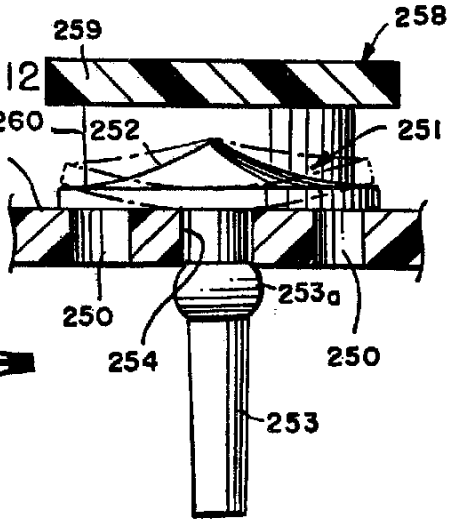


FIG. 9

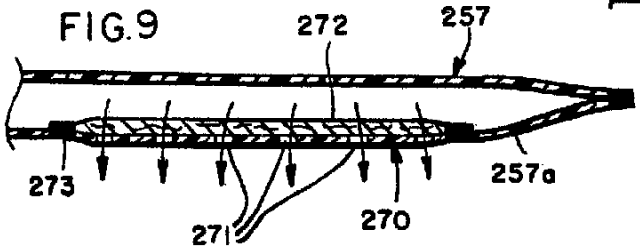


FIG. 13

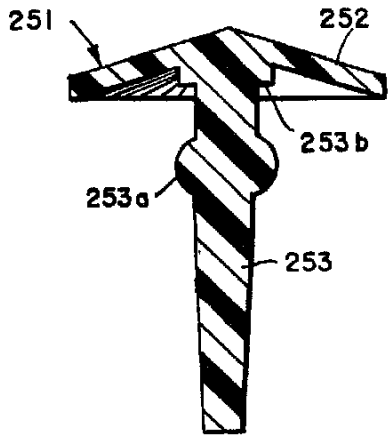


FIG. 14

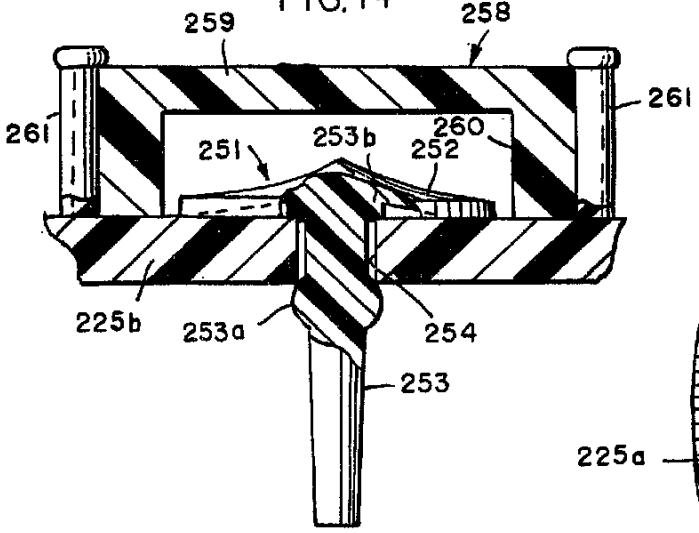


FIG. 15

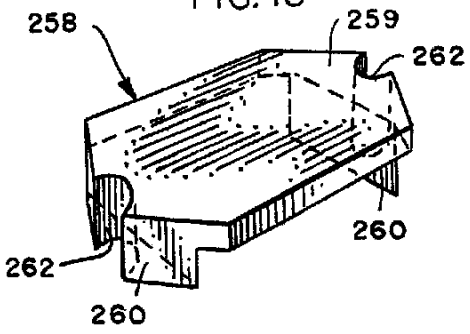
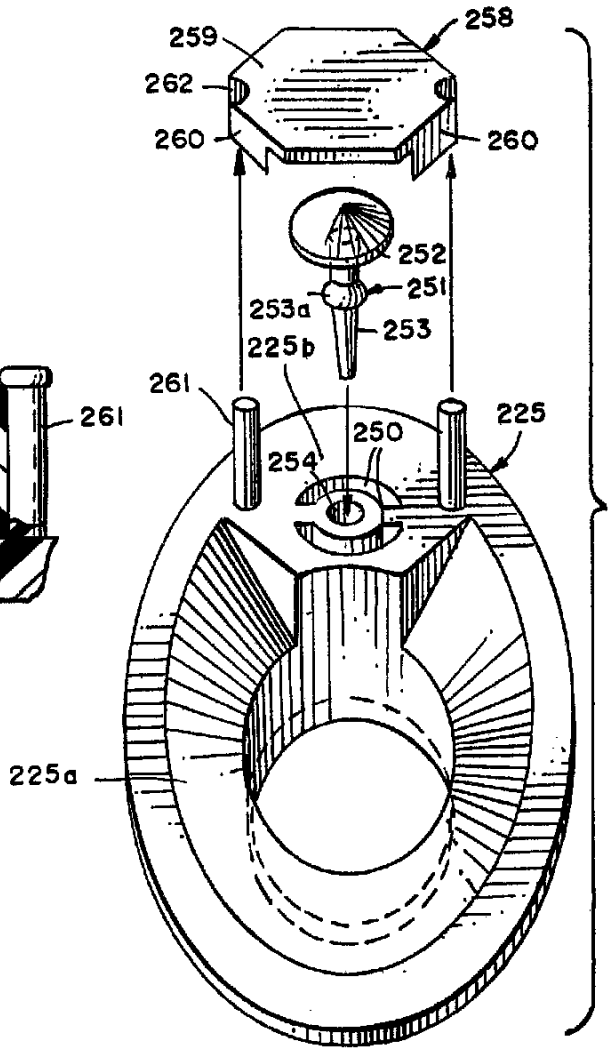


FIG. 16



SPECIFICATION

Female urinary incontinence device

The present invention relates to a female urinary incontinence device.

Various devices have been proposed in past years for directing and collecting urine from female patients suffering from urinary incontinence but, in general, such devices have been associated with problems of leakage, wearer discomfort, pressure sores, and even necrosis. An indication of the ineffectiveness of such prior devices lies in their lack of commercial success.

The problems associated with prior devices are particularly pronounced with ambulatory patients because of the varied and complex anatomical changes that occur in the periurethral area during locomotion and the failure of such devices to adapt to such changes. However, the need for an effective device is by no means limited to ambulatory patients. For example, non-ambulatory female patients with spinal cord injuries are not served well by existing devices (indwelling catheters, intermittent catheters, diapers, etc.) despite only minimal body movement of such patients.

Prior patents have disclosed female urinary collection devices equipped with locating elements intended to be inserted into the vagina for retaining the collection devices in operative positions. Reference may be had to US Patents 2,483,079, 2,490,969, 3,116,734, 3,528,423, 3,512,185, 3,776,235, 3,661,155, and 4,246,901. Those constructions in which the locating elements are relatively rigid clearly fail to conform with the anatomical changes occurring during body movement. While prior devices with flexible or deformable vaginal locating elements may reduce tissue irritation and increase patient comfort, problems in providing an effective seal and avoiding leakage along the lines or zones of contact have nevertheless remained.

Other patents of interest are US 4,270,539, 3,651,810, 4,198,979, and 3,194,238.

One aspect of this invention lies in the discovery that effective sealing engagement with perimeatal tissues may be achieved if the female incontinence device is constructed so that the periurethral cup is compressible but generally form-retaining and is mounted so that it may move independently, at least to a limited extent, with respect to those portions of the device that make external contact with the wearer. A further aspect lies in the recognition that if such a moulded compressible element is cup-shaped in configuration and is operatively connected to an external pad (which is in turn held in place by a panty or supporting belts) by means of a tubular elastic bellows that exerts an upward force of the cup when the device is worn without, at the same time, interfering with limited independent movement of the cup with respect to the pad, such a combination will result in a device that eliminates or substantially reduces the aforementioned problems associated with prior devices. An air entry port, normally closed by a one-way valve, allows air to enter the system to prevent the development of relative negative pressure within that system, and a vent is provided in the collector to prevent expansion or deformation of the collector (normally an expandable plastics pouch) that might otherwise result from entrapped air and the development of a relative positive pressure.

The periurethral cup of a device embodying this invention is moulded in one piece of soft, compressible but generally form-retaining material having a durometer (hereinafter: hardness) within the range of about 1 to 30 on the Shore A scale, the preferred range being approximately 5 to 20 and a suitable value being about 10 on that scale. An elastomeric material, moulded so that the outer surfaces of the cup are smooth, and non-porous, has been found particularly effective.

The periurethral cup is provided with front, rear, and lateral wall portions defining upper and lower openings, such wall portions having a substantial wall thickness (about 3 to 15 millimetres) and having smoothly rounded surfaces, for making substantial surface contact with the periurethral floor and vaginal introitus. The rear wall portion extends upwardly beyond the upper limits of the front and lateral portions to define a resilient, vaginally-insertable, urine-deflecting protuberance, a feature of importance for those patients whose urethral orifice is located in, or immediately adjacent to, the vaginal introitus. The urine-deflecting protuberance is capable of flexing towards and away from the entrance opening of the cup without causing buckling or kinking of the smoothly-rounded contact surfaces engaging the periurethral floor and vaginal introitus because of the compessibility and substantial wall thickness of the cup.

An external pad of soft, resilient and flexible material is dimensioned for externally contacting the labia majora of the wearer and has an opening extending therethrough. Between that opening and the lower opening of the periurethral cup is a tubular elastic bellows dimensioned for exerting an upward force on the cup, when the device is worn, to maintain an effective seal between the rounded contact surfaces of the cup and the surfaces of the periurethral floor and introitus despite the complex anatomical changes or displacements that occur during the dynamics of body movement. The length of the elastic bellows varies within certain predetermined limits according to the distance between the periurethral floor and the external surfaces of the labia majora for each wearer, and a sizing instrument, patterned after the construction of the urinary incontinence device, may be used to establish the proper bellows length for a given patient. Such sizing tool is designed to allow endoscopic examination if deemed necessary or desirable.

The external pad may, if desired, be provided with a soft absorbent liner for directly contacting the labia majora of the patient. Flexible tubing

extends from the outlet of the external pad to a leg bag or other suitable collection device. The external pad is preferably held in place by the wearer's undergarment (panty), but other supporting means in the forms of straps or belts may be used.

The invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of a female urinary incontinence device embodying the invention;

Figure 2 is a vertical longitudinal sectional view of the device;

Figure 3 is an enlarged cross sectional view taken along line 3—3 of Figure 2;

Figure 4 is a saggital sectional view illustrating the device as it is worn;

Figure 5 is a saggital sectional view similar to Figure 4 but illustrating the relative displacements of the external pad and periurethral cup during wearer movement;

Figure 6 is a lateral sectional view of the device as it is worn;

Figure 7 is a side elevational view, shown partly in section, of a sizing tool adapted to be used as part of the present invention;

Figure 8 is a fragmentary side view, taken partly in section, showing a modified device with ports or vents for preventing collapse of the bellows and conduit while at the same time allowing gas to escape from the pouch;

Figure 9 is an enlarged horizontal cross sectional view of the pouch's vent and filter, with certain elements of the pouch and associated coupling omitted for clarity of illustration;

Figure 10 is an enlarged vertical sectional view of certain portions of the device depicted in Figure 8;

Figure 11 is a horizontal sectional view taken along line 11—11 of Figure 10;

Figure 12 is a still further enlarged sectional view of the inlet port and valve member taken along line 12—12 of Figure 11;

Figure 13 is a sectional view of the umbrella valve member showing details of construction thereof;

Figure 14 is an enlarged sectional view taken along line 14—14 of Figure 11;

Figure 15 is a perspective view of a fluid-deflecting element; and

Figure 16 is an exploded perspective view of the valve member, fluid deflector, and the portion of the device providing the valve passage or port.

Referring to the embodiment shown in Figures 1—6, the primary components of the female urinary incontinence device 10 are a periurethral cup 11, an external pad 12, and tubular elastic bellows 13. A flexible tube 14 carries urine to a suitable collector or receptacle 15. For an ambulatory patient, the collector 15 would ordinarily take the form of a leg bag, such as the bag disclosed in co-owned US patent application Serial No. 273,363, filed June 15, 1981. It is to be understood, however, that other types of collectors might be provided to suit the needs and physical condition of the user. Ordinarily, the flexible tube 14 would include a suitable detachable coupling 16. The coupling 16 illustrated in Figure 2 is similar to that shown and described in US patent 4,280,498, but other types of couplings may be provided.

The periurethral cup 11 is moulded in one piece from a soft, compressible, by generally form-retaining material. A moulded elastomeric silicone material having a smooth, substantially non-porous outer surface has been found particularly effective, but other moulded compressible materials, such as elastomeric foam materials, might be used. Regardless of the material selected, it is believed critical that such material should have a hardness within the range of about 1 to 30 on the Shore A scale, preferably within the range of 5 to 20. Particularly effective results have been obtained with a material having a hardness of approximately 10 on that scale.

It is also important that the side walls of the periurethral cup 11 have substantial thickness and that the uppermost surfaces of the cup be smoothly curved or rounded as shown most clearly in Figures 2 and 3. More specifically, as depicted in the drawings, the cup 11 has upper and lower openings 17 and 18, respectively. The integral side wall 19 of the cup is composed of front, rear, and lateral wall portions 19a, 19b, and 19c, respectively. In the region bordering the top opening 17, each of those wall portions should have a thickness d (Figure 3) within the range of about 3 to 15 millimetres. The result is a cup which, as brought out hereinafter, has upper surfaces making substantial contact with the periurethral floor and vaginal introitus and which, although soft and compressible, tends to be shape-retentive in use notwithstanding the upward force exerted by the elastic bellows 13.

The rear wall portion 19b curves upwardly beyond the upper limits of the front and lateral wall portions 19a, 19c to define a resilient, vaginally-insertable, urine-deflecting extension or protuberance 20. The essential purpose of the protuberance 20 is to serve as a urine deflector for that portion of the female population, estimated at between 15 to 20%, whose urethral orifice is located within, or immediately adjacent to, the vaginal introitus. Any functions the protuberance performs in locating and retaining the cup in position are of secondary significance. As described more fully hereinafter, the wide smoothly-rounded contact surfaces of the compressible cup, in combination with the gentle upward force exerted by the elastic bellows 13, serve primarily to maintain the cup is its operative position.

As shown in Figures 1—3, the rounded upper surfaces 20a of the protuberance 20 merge smoothly and gradually with the upper surfaces 11a of the remaining side and front wall portions of the cup 11. Specifically, the upper front surfaces of the protuberance 20 merge with the upper surfaces of the side walls 19c along a

curved line represented in Figure 2 as having a substantial radius r. That radius would normally fall within the range of about 5 to 12 millimetres. Of particular significance is the fact that even when the protuberance is urged forwardly, as indicated by broken lines in Figure 2, no buckling or kinking of the wall occurs at radius r because of the compressibility of the material from which the cup is formed. Consequently, an effective seal between the curved upper surfaces of the cup (including the protuberance) and the contact surfaces of the patient tends to be maintained during normal body movement.

The external pad 12 may be formed of the same soft, compressible material as the periurethral cup 11 and, in any event, should be formed of a resilient, flexible polymeric material. The pad 12 is generally oval in outline, substantially larger than the cup 11, and has a passage or opening 21 extending therethrough (Figure 2). As shown in the drawings, the external pad 12 has an upper surface 12a that is preferably concave or dish-shaped and, if desired, the upper surface may support an annular absorbent liner 22 (Figure 2) formed of non-woven cotton fibres or other suitable absorbent material. Along its lower or external surface 12b, pad 12 may be provided with attachment means 23 in the form of fabric having nylon hooks or loops of the type commercially available under the trade name Velcro. If such retaining means is used, then the patient would also wear a panty having a brushed nylon crotch panel for engaging and interlocking with attachment means 23, thereby helping to maintain the external pad 12 against the outer surfaces of the labis majora.

The bellows 13 may be formed of any suitable elastomeric material and, in an uncompressed or extended state, assumes the appearance depicted in Figures 1—3. The number of corrugations or convolutions 13a of the bellows for any given urinary collection appliance will depend on the distance between the labis majora and the periurethral floor of the wearer to be fitted with the device so that, when worn, the corrugations will be compressed or axially reduced as indicated in Figures 4 and 6. Ordinarily, for adult wearers, the number of corrugations will range between 2 (Figure 2) and 6, and the undeformed length of the corrugated portion will range from 10 to 50 millimetres, with 3 selected sizes within those ranges meeting the requirements for over 90% of the adult female population. The tubular bellows 13 may be formed of elastomers of polyurethane, silicone rubber, latex, or any of a variety of other materials having similar properties. A particularly effective material has been found to be a silicone rubber marketed by Dow Corning, Midland, Michigan, under the designation Q7-4840; another, available from the same source, is MDX4-4210.

In the embodiment shown, the bellows 13 and cup 11 are formed separately and the upper end of the bellows 13 is then secured by adhesive or by any other suitable means to the cup 11 about the lower opening 18; however, it is to be understood that, if desired, the two elements may be formed integrally. The lower end of the bellows 13 is connected to the flexible tube or conduit 14 at the upper end of the opening 21 of the external pad 12 by means of an upwardly-flared extension 25 of the conduit 14. The extension 25 of the conduit 14 may be joined to the bellows 13, and to the wall of external pad 12, by adhesives, heat sealing, or any other suitable means.

Figures 4—6 depict the anatomical orientation of the urinary incontinence device 10 under normal conditions of use. The external pad 12 bears upwardly against the external surfaces of the labia majora 30 and is held in that position by a panty or other support means (not shown) extending beneath the external pad 12 and interlocked with the annular patch 23 (if provided). The periurethral cup 11 extends upwardly between the labia majora 31, and its soft rounded upper surfaces 11a of the front and side wall portions 19a and 19c engage the periurethral floor 32 about the meatus of the urethra 33. The urine-deflecting protuberance 20 extends upwardly a short distance into the introitus of the vagina 34. The gently-rounded upper surfaces 20a and 11a of the periurethral cup 11 therefore make resilient sealing contact with the periurethral meatal surfaces even in the minority of cases where the patient's urethra curves rearwardly and communicates directly with the introitus (as represented in broken lines 35 in Figure 4). The wide smoothly-rounded upper surfaces of the cup 11 make substantial surface contact with the wearer and greatly reduce the possibility of localizing of forces that might result in discomfort and pressure necrosis. The thickness of the cup's walls yield a form-retaining construction despite the softness and compressibility of the material from which the cup is formed. Should limited deformation of the cup 11 occur in use (as indicated, for example, by broken lines in Figure 2), such deformation can be accommodated by the compressibility of the material of the cup 11 without accompanying buckling or kinking actions that might result in leakage, and without relative movement between body tissues and the cup surfaces that might produce irritation and discomfort.

It is to be emphasized that the form-retentive cup 11 is urged upwardly into sealing contact with the periurethral floor 32 and introitus because of the expansive force exerted by the elastomeric bellows 13. When the urinary incontinence device is properly worn, the bellows 13 is in a partially compressed state as shown most clearly in Figures 4 and 6. The external pad 12 is immobilzed against labia majora 30 and functions as a base against which the expansive force of the bellows 13 is applied in a downward direction. The upward force exerted by the cup 11 against the periurethral surfaces is therefore relatively constant in magnitude and direction.

The bellows 13 not only exerts a constant gentle upward force on the cup 11, to maintain

the cup in the position illustrated, but also is capable of twisting, bending, and deflecting to accommodate changes in position of the external pad 12 and internal cup 11 resulting from the dynamics of body movement. Figure 5 illustrates what is believed to be a typical condition where, because of wearer movement, the cup 11 and pad 12 have become laterally disposed but, nevertheless, the expansive force exerted by the bellows 13 coupled with the substantial contact surfaces between the form-retentive but compressible cup 11 and the periurethral surfaces still maintain the cup in sealing contact with the wearer.

Figure 7 illustrates a sizing instrument 40 that may be conveniently used for establishing the bellows length required for properly fitting a wearer with the urinary collection device 10. Periurethral cup 111 is of substantially the same size and shape as cup 11 previously described, the essential difference being that the cup 111 is secured or formed at the upper end of a stiff calibrated tube 41 rather than extending from a resilient bellows 13. The external pad 112 may be similar to previously-described pad 12, being formed of a resilient elastomeric material (Dow Corning Q7-4840 has been found particularly effective) and having essentially the same dimensions. The primary difference is that instead of being secured to the bellows 13 and flexible tube 14, the external pad 112 may be provided with a sleeve 42 that slidably receives the rigid calibrated tube 41. The external pad 112 may therefore be slid along the length of the tube 41, and its position established by reference to calibration lines 43 and numerical indicia 44 on the tube 41.

The sizing instrument 40 may be disposable and is used by a doctor or other medically-trained personnel by inserting periurethral cup 111 into the position assumed by cup 11 in Figure 4, and then sliding the external pad 112 axially along the indexed tube 41 until the pad bears against the labia majora 30 in the same manner shown in Figure 4 for pad 12. If inspection is deemed necessary or desirable to establish that the periurethral cup 111 is properly seated against the periurethral floor and vaginal introitus, or if inspection is required for any other reason, the doctor may insert the stem of a conventional endoscope through the passage 45 of the tube 41, so that the objective of the endoscope extends into the open cup 112. Once it is determined that both the periurethral cup 111 and the external pad 112 are properly positioned, the sizing instrument is removed and the determination of bellows length for the collection device 10 to be used by the patient is made from scale 43—44.

The following example details the preparation of a soft, compressible material, and the construction of a periurethral cup formed of such material, found to be particularly effective for use in practising the invention: Ten parts by weight of a first component and 7 parts by weight of a second component of a two-part silicone rubber addition polymerization system, type Q7-4840 from Dow Corning, Midland, Michigan, were mixed with 1.7 parts by weight of type 360 Dow Corning silicone fluid having a viscosity of about 350 cP (= 0.35 Pa.s), and then degassed and injected into moulds for the periurethral cup 11, the external pad 12, and bellows 13. Curing was achieved by heating to a temperature of 200—400°F (=93.3 to 204.4°C) for an interval of up to about 6 minutes. The silicone rubber of the final parts was homogeneous, smooth and clear (semi-transparent), with a hardness of approximately 10 on the Shore A scale.

The parts may also be fabricated from an elastomeric foam as follows: Four parts by weight of a silicone foam base, type Q7-4290 from Dow Corning, Midland, Michigan, having a viscosity within the range of 1,000 to 6,000 cP (=1 to 6Pa.s), and 2.5 parts by weight of Silastic 382 elastomer from the same source, having a viscosity within the range of 35,000 to 65,000 cP (=35 to 65 Pa.s), were mixed thoroughly and 0.045 parts of a silicone foam catalyst, type Q7-4290, was then added and mixed thoroughly for approximately 30 seconds. The mixture was allowed to degas for approximately 30 seconds and then stirred vigorously. The degassing and stirring procedures were repeated twice, and the mixture was then immediately poured into moulds for the periurethral cup 11 and the external pad 12. The cup and pad were removed from their respective mould cavities from a curing interval of approximately 12 minutes. The facilitate removal, the cavities of the moulds were pre-coated with a suitable mould release agent (HEM 41220). The small cell size of the foam parts were promoted by the degasing procedures and the vigorous stirring action. The final parts had smooth, substantially non-porous outer surfaces or skins and a hardness of approximately 10 in the Shore A scale.

The embodiment depicted in Figures 8—16 is essentially the same as the embodiment of Figures 1—6 except for air porting and gas venting means. The device includes an external pad 212 for contacting the labia majora of the wearer, a periurethral cup 211 having upper and lower openings 217 and 218, respectively, and a tubular elastic bellows 213 extending between the lower opening of the cup and the opening of the external pad for urging the cup into engagement with the periurethral floor and vaginal introitus when the pad is held against the labia majora. The cup 211 has an integral side wall 219 comprised of front, rear, and lateral wall portions 219a, 219b, and 219c, respectively. In the region bordering the top opening 217, each of those wall portions has smoothly rounded surfaces and has a substantial thickness within the range of about 3 to 15 millimetres. The rear wall portion 219b curves upwardly beyond the upper limits of the front and lateral wall portions to define the resilient, vaginally-insertable, urine-deflecting extension or protuberance 220. All of the characteristics, compositions, dimensions, and functions of the cup, bellows, and pad in this embodiment are

essentially the same as those described in connection with the first embodiment of Figures 1—6.

Whether the bellows 213 and cup 211 are formed separately (and then joined by adhesive or any other suitable means, as shown and previously described) or integrally, the upper end of the bellows 213 communicates directly with the periurethral cup 211 at the lower opening 218. The lower end of the bellows 213 is connected to the upper end of a flexible conduit or tube 214 by an extension 225 of that conduit. As shown most clearly in Figures 8 and 10, the interfacial conduit extension 225 has a wall 225a that flares upwardly and outwardly to match the larger diameter of the bellows 213. However, one portion 225b of that wall extends generally horizontally, that is, in a plane normal to the axis of the bellows in an undeformed state. One or more air entry ports 250 extend vertically (i.e. axially) through the wall portion 225b; in the form shown, two such ports 250 are provided, each having an arcuate configuration when viewed in transverse section or plan (Figure 11). Vavle means 251, which may take the form of an umbrella valve having a conical canopy portion 252 and stem portion 253, is positioned to allow entry of ambient air while at the same time blocking the escape of fluids (gases and liquids) from the bellows 213 and upper end of the conduit 214. As shown most clearly in Figures 12—14, the elongate stem 253 of the valve member 251 is adapted to extend downwardly through an opening 254 in the wall portion 225b, such opening being centred between the arcuate ports 250. An intermediate enlargement 253a of the stem 253 serves to limit upward movement of the stem with respect to the wall portion 225b; downward movement is prevented by an upper enlargement 253b of the stem 253 shrouded by the conical canopy portion 252.

The umbrella valve member 251 is composed of a soft, easily-deformable and readily-recoverable elastic material such as, for example, silicone rubber. Figure 13 depicts the valve member in an untensioned or undeformed state, but it will be noted from Figure 14 that when the valve member is secured to apertured wall 225b of the interfacial conduit extension 225 the valve member is in a pre-tensioned or pre-loaded condition with canopy portion 252 having a distinctive downward and outward curvature and with the peripheral edge of the canopy portion held in normal sealing engagement with the upper surface of the wall 225b. Because of its deformability, and notwithstanding the pre-tensioning, the canopy portion 252 of the valve member is capable of flexing upwardly to allow entry of air into the system when even a small pressure differential, for example, 0.5 inches H_2O (=124.5 Pa) exists. Such upward flexure is indicated in broken lines in Figure 12. On the other hand, should the pressure within the system be equal to or exceed the ambient pressure, the highly flexible canopy 252 will effectively seal against the upper surface of wall portion 225b and will block exit of fluids, at least within the range of pressure differentials encountered in normal use of the device. As shown in Figure 10, the external pad 212 has an inlet passage 225 communicating with the ports 250 in the wall portion 225b. The passage 255 extends upwardly through the wall of the pad 212 from an entrance 256 at the pad's lower end.

The purpose of the ports 250 and valve members 251 is to ensure that the superior sealing action of the periurethral cup against the periurethral floor and vaginal introitus will not interfere with proper flow of urine through the conduit 214 to the pouch or collection device 257. If it were not for the inlet ports, a column of liquid flowing downwardly through the conduit 214 would generate a relative negative pressure that might even be sufficient to collapse the bellows 213 and/or conduit 214, interfere with the fit of the periurethral cup 211, and possibly result in leakage and wearer discomfort. Since the ports 250 and the one-way valve 251 permit the entry of air at the upper end of the conduit, pressure is equalized and such problems are thereby avoided.

While the umbrella valve construction shown in the drawings has been found highly effective, other types of air-inletting valves might be used. Furthermore, where an umbrella valve is utilized, it may or may not be used in conjunction with deflector means 258. The purpose of the deflector is simply to prevent the possibility that leakage might occur should canopy 252 of the valve member 251 be impacted by a stream of urine flowing rapidly through the bellows 213 and entering conduit 214. If the possibilities of leakage caused by urine impinging upon and deforming the valve member are considered so slight as to be negligible or inconsequential then deflector 258 may be eliminated.

As shown in Figures 12 and 14—16, the deflector 258 takes the form of a plate 259 having a pair of spaced downwardly-extending legs 260. The cover plate 259 extends over the canopy 252 of the valve member 251 and is held in place by upstanding spindles or lugs 261 that are formed integrally with the interfacial conduit extension 225 and received within channels or holes 262 formed in the legs 260 of the deflector 258. The deflector 258 may be frictionally held in place by the lugs 261 and, as shown, the free ends of the lugs 261 may be flattened and thereby laterally enlarged to lock the deflector 258 in operative position. Alternatively, the parts may be permanently bonded or fused together by any suitable means.

To prevent air which enters the system through the ports 250 from inflating the pouch 257, a wall 257a of the pouch is provided at its upper end with air venting means 270 (Figs. 8 and 9). Any suitable means for venting air from the upper end of the pouch while at the same time blocking the outflow of liquid may be used. In the embodiment illustrated, the venting means takes the form of perforations 271 formed in the wall 257a with the

area of such perforations backed by a thermoplastic microporous strip 272 capable of allowing gases to escape from the pouch while at the same time blocking the passage of urine. The strip or patch 272 is perimetrically sealed to the wall of the pouch by heat sealing 273 or by any other suitable sealing means. While various types of hydrophobic microporous materials may be used for fabrication of the vent or filter patch 272, effective results have been achieved using 3-micron filter stock marketed under the designation "Versapor" by Gelman Corporation, Ann Arbor, Michigan.

The lower or distal end of flexible conduit 214 is shown to be connected to the pouch 257 by a detachable coupling 280 of the type shown and described in co-owned US patent 4,280,498. Reference may also be had to copending US patent application serial No. 273,363, filed June 15, 1981, for a manner of forming an effective liquid-tight seal between the conduit and the pouch while, at the same time, allowing limited pivotal action between the conduit and pouch. Since any of a variety of couplings and connections between the conduit and the pouch might be provided, all within the knowledge of someone familiar with urine collection systems, a discussion of such structures in further detail is believed unnecessary herein.

While in the foregoing we have disclosed embodiments of the invention in considerable detail for purposes of illustration, it will be understood by those skilled in the art that many of these details may be varied without departing from the scope of the attached claims.

CLAIMS

1. A female urinary incontinence device comprising an external pad of flexible, resilient material for externally contacting the labia majora of a wearer, said pad having an opening therethrough; a periurethral cup moulded of soft compressible material and having an upper opening defined by smoothly-rounded contact surfaces adapted to engage the periurethral floor and vaginal introitus of a wearer; said compressible material having a durometer within the range of about 1 to 30 on the Shore A scale; said cup also having a lower opening; and a tubular elastic bellows extending between said lower opening of said cup and said opening of said pad for urging said cup into engagement with said periurethral floor and vaginal introitus when said pad is held against the labia majora.

2. A device according to Claim 1, in which retaining means are provided for holding said pad against the labia majora of a wearer.

3. A device according to Claim 1 or 2, in which said cup includes front, rear, and side wall portions having upper surfaces merging smoothly with each other and being of rounded cross-sectional contour to provide wide gently-curved contact surfaces for sealingly engaging the periurethral floor and vaginal introitus of a wearer.

4. A device according to Claim 3, in which said rear wall portion extends upwardly beyond said front and side wall portions to define a resilient vaginally-insertable urine-deflecting protuberance.

5. A device according to Claim 4, in which said urine-deflecting protuberance is capable of flexing towards and away from said upper opening without causing buckling or kinking of the contact surfaces of said cup at the merger of said side and rear wall portions because of the compressibility and substantial wall thickness of the cup.

6. A device according to any one of Claims 3 to 5, in which said wall portions of said periurethral cup have thicknesses adjacent said upper opening within the range of about 3 to 15 millimetres.

7. A device according to any one of Claims 1 to 6, in which said material of said cup has a hardness within the range of the order of 5 to 20 on the Shore A scale.

8. A device according to Claim 7, in which said material of said cup has a hardness of the order of 10.

9. A device according to any one of Claims 1 to 8, in which said material of said cup is silicone rubber.

10. A device according to any one of Claims 1 to 8, in which said material of said cup is an elastomeric foam.

11. A device according to any one of Claims 1 to 10, in which said pad includes a soft, absorbent removable liner for engaging the labia majora of a wearer.

12. A female urinary incontinence device comprising an external pad of flexible, resilient material having a concave upper surface for externally contacting the labia majora and having an opening extending therethrough; a periurethral cup moulded of soft, compressible material having front, rear, and side wall portions with upper surfaces merging smoothly with each other and being of rounded cross-sectional contour to provide wide, curved contact surfaces for engaging the periurethral floor and vaginal introitus; said rear wall portion extending upwardly and beyond said front and side wall portions to define a resilient, vaginally-insertable, urine-deflecting protuberance; said compressible material of said periurethral cup having a durometer within the range of about 1 to 30 on the Shore A scale; said protuberance being capable of flexing towards and away from said upper opening without causing buckling or kinking of said contact surface of said cup at the merger of said side and rear wall portions; said cup also having a lower opening; and a tubular elastic bellows extending between said lower opening of said cup and said opening of said pad for urging said cup into engagement with the periurethral floor and vaginal introitus when said pad is supported against the labia majora.

13. A device according to Claim 12, in which said material of said cup has a hardness within the range of about 5 to 20 on the Shore A scale.

14. A device according to Claim 13, in which said material of said cup has a hardness of approximately 10 on the Shore A scale.

15. A device according to any one of Claims 12 to 14, in which said material of said cup is silicone rubber.

16. A device according to any one of Claims 12 to 14, in which said material of said cup is elastomeric foam.

17. A device according to Claim 16, in which said elastomeric form of said cup has a substantially non-porous outer skin.

18. A device according to any one of Claims 12 to 17, in which said wall portions of said periurethral cup have thicknesses within the range of about 3 to 15 millimetres.

19. A device according to any one of Claims 12 to 18, in which retaining means are provided for holding said external pad in position against the labia majora.

20. A device according to Claim 19, in which said retaining means comprises a panty; and releasably interlocking means provided by said panty and the undersurface of said pad for securing said panty and pad against relative movement.

21. A device according to any one of Claims 12 to 20, in which a flexible tube has one end secured to said external pad at the opening thereof; and receptacle means communicating with the opposite end of said tube.

22. A device according to any one of Claims 12 to 21, in which said concave surface of said external pad supports an annular liner of soft, absorbent material for engaging the labia majora.

23. A device according to any one of Claims 12 to 22, in which said elastic bellows has from 2 to 6 corrugations and an undeformed length of from 10 to 50 millimetres.

24. A sizing instrument for the urinary incontinence device of Claims 1 to 12, comprising a second periurethral cup substantially identical to said first-mentioned periurethral cup; a relatively stiff, elongate member secured to an projecting downwardly from said second cup; said member having calibration marks along the outer surface thereof; and a second external pad similar to said first-mentioned external pad and slidably mounted for movement upwardly and downwardly along said member; whereby, by positioning said second periurethral cup of said instrument against the periurethral floor and vaginal introitus, and then sliding said second external pad into contact with the labia majora, the distance beween the second cup and second pad, as indicated by the calibration on said member, may be used to determine the proper length of said tubular elastic bellows for a patient on whom said instrument is used.

25. An instrument according to Claim 24, in which said elongate member is tubular; whereby, an endoscope stem may be inserted through said member and into said cup for cystoscopic observation of a patient when said instrument is in place.

26. A female urinary incontinence device comprising an external pad of flexible, resilient material for externally contacting the labia majora of a wearer, said pad having an opening therethrough; a periurethral cup moulded of soft compressible material and having an upper opening defined by smoothly-rounded contact surfaces adapted to engage the periurethral floor and vaginal introitus of a wearer; said compressible material having a hardness within the range of about 1 to 30 on the Shore A scale; said cup also having a lower opening; tubular elastic bellows extending between said lower opening of said cup and said opening of said pad for urging said cup into engagement with said periurethral floor and vaginal introitus when said pad is held against the labia majora; conduit means extending into said opening of said pad and joined to, and communicating with, the lower end of said bellows; said conduit means including a wall having a port extending therethrough; and one-way valve means associated with said port for allowing air to enter said conduit means while at the same time preventing the escape of fluids therefrom.

27. A device according to Claim 26, in which a urine collection pouch is connected to said conduit means; said pouch being provided with a wall having a gas vent extending therethrough; and means for preventing the escape of liquids from said pouch through said vent.

28. A device according to Claim 26 or 27, in which retaining means are provided for holding said pad against the labia majora of a wearer.

29. A device according to any one of Claims 26 to 28, in which said cup includes front, rear, and side wall portions having upper surfaces merging smoothly with each other and being of rounded cross-sectional contour to provide wide gently-curved contact surfaces for sealingly engaging the periurethral floor and vaginal introitus of a wearer.

30. A device according to Claim 29, in which said rear wall portion extends upwardly beyond said front and side wall portions to define a resilient vaginally-insertable urine-deflecting protuberance.

31. A device according to Claim 30, in which said urine-deflecting protuberance is capable of flexing towards and away from said upper opening without causing buckling or kinking of the contact surfaces of said cup at the merger of said side and rear wall portions because of the compressibility and substantial wall thickness of said cup.

32. A device according to any one of Claims 29 to 31, in which said wall portions of said periurethral cup have thicknesses adjacent said upper opening within the range of about 3 to 15 milimetres.

33. A device according to any one of Claims 26 to 32, in which said material of said cup has a hardness within the range of about 5 to 20 on the Shore A scale.

34. A device according to Claim 33, in which said material of said cup has a hardness of approximately 10.

35. A device according to any one of Claims 26 to 34, in which said material of said cup is an elastomeric foam.

36. A female urinary incontinence device comprising an external pad of flexible, resilient material having a concave upper surface for externally contacting the labia majora and having an opening extending therethrough; a periurethral cup moulded of soft, compressible material having front, rear, and side wall portions with upper surfaces merging smoothly with each other and being of rounded cross-sectional contour to provide wide, curved contact surfaces for engaging the periurethral floor and vaginal introitus; said rear wall portion extending upwardly beyond said front and side wall portions to define a resilient, vaginally-insertable, urine-deflecting protuberance; said compressible material of said periurethral cup having a hardness within the range of about 1 to 30 on the Shore A scale; said protuberance being capable of flexing towards and away from said upper opening without causing buckling or kinking of said contact surface of said cup at the merger of said side and rear wall portions; said cup also having a lower opening; tubular elastic bellows extending between said lower opening of said cup and said opening of said pad for urging said cup into engagement with the periurethral floor and vaginal introitus when said pad is supported against the labia majora; conduit means extending into said opening of said pad and joined to, and communicating with, the lower end of said bellows; said conduit means including a wall having a port extending therethrough; and one-way valve means connected to said wall for allowing ambient air to enter said conduit means while at the same time preventing the escape of fluids therefrom.

37. A device according to Claim 36, in which a urine collection pouch is connected to said conduit means; said pouch being provided with a wall having a gas vent extending therethrough; and means for blocking the escape of liquids from said pouch while allowing gases to pass through said vent.

38. A device according to Claim 36 or 37, in which said material of said cup has a hardness within the range of about 5 to 20 on the Shore A scale.

39. A device according to Claim 38, in which said material of said cup has a hardness of approximately 10 on the Shore A scale.

40. A device according to any one of Claims 36 to 39, in which said material of said cup is silicone rubber.

41. A device according to any one of Claims 36 to 38, in which said material of said cup is elastomeric foam.

42. A device according to Claim 41, in which said elastomeric foam of said cup has substantially non-porous outer skin.

43. A device according to any one of Claims 36 to 42, in which said wall portions of said periurethral cup have thicknesses within the range of about 3 to 15 millimetres.

44. A female urinary incontinence device constructed, arranged and adapted to operate substantially as herein described with reference to, and as shown in, Figures 1 to 6 and 8 to 16 of the accompanying drawings.

45. A fixing instrument for a female urinary incontinence device constructed, arranged and adapted to operate substantially as herein described with reference to, and as shown in, Figure 7 of the accompanying drawings.

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